market authorization was retrieved from the EMA or MHRA. NICE positive decisions were compared to the market authorizations. Any decision that included language that restricted the population eligible for reimbursement for a given therapy was categorized as "recommend with restrictions." NICE positive decisions that were not more restrictive than the market authorization were categorized as "recommend." Negative decisions were categorized as "do not recommend." Restrictions were also quantified and categorized. **RESULTS:** NICE issued "do not recommend" decisions in 32% of the reviews from 2007-2013. The overall rate at which NICE issued "do not recommend" decisions increased after 2010, but this did not pass traditional levels of statistical significance (p=.21). NICE issued positive decisions in 68% of reviews, but the decision was more restrictive than the market authorization in 52% of the positive decisions. NICE's restrictiveness has decreased since 2007, with the exception of 2013 where 60% of NICE's positive decisions were "recommend with restrictions." For the "recommend with restrictions" reviews, there are 1.7 restrictions on average (range 1-4, s.d. 11) added to the market authorization. The most prevalent type of restrictions were for contraindicated or intolerance." **CONCLUSIONS:** In 2007-2013, NICE issued "recommend with restrictions" decisions in 36% of reviews and issued both "recommend" and "do not recommend" decisions in 32% of reviews. NICE was more restrictive than the market authorization in 52% of the positive decisions, though NICE's restrictiveness seems to be declining over time. An independent analysis of NICE decisions in 2007-2013 found a statistically significant different distribution of decisions than reported in the NICE website (p=.01).

PHP207

MULTICRITERIA DECISION ANALYSIS (MCDA) IN HTA – PILOT STUDY IN THE CZECH REPUBLIC

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OBJECTIVES: Multicriteria Decision Analysis (MCDA) is an analytical quantitative instrument focused on supporting the decision-making process between alternative products based on multiple criteria. **METHODS:** In the pilot study on MCDA application in HTA in the Czech Republic, the following criteria were chosen by the experts: efficacy/effectiveness, safety, budget impact, disease severity, cost effectiveness and unmet needs. The number of evaluators was 10. Each evaluator determined weights within the range from 1 to 10 (from the least to the most important). The resultant weights were displayed as an arithmetic mean of weights of the individual evaluators and as a trimmed mean with the minimum and maximum values discarded. The weights were also calculated by discarding the last evaluator, i.e. there were 4 sets of weights examined, each time normalized by 100%. **RESULTS:** Each evaluator rated 5 chosen medicines with weights 0, 1, 2, 3 within the chosen categories. Afterwards, the mean scores and trimmed means with the lowest and the highest values discarded were determined for each of the 5 medicinal products chosen. All 8 estimates (4 weights times 2 mean scores) lead to the identical classification of medicinal products which proves the robustness of the approach. The biggest divergences between the evaluators' assessment of the same medicinal product was observed in case of its safety, whereas the slightest were considered the budget impact and cost-effectiveness. On the other hand, the differences in the cost-effectiveness assessment of the 5 medicinal products considered were followed by the greatest discrepancies as regards the budget impact. The MCDA s was compared with the classifications of the medicinal products based on the ICER only which revealed significant differences (e.g., 2nd place according to the ICER vs. 5th according to the MCDA). **CONCLUSIONS:** The MCDA brings new information with respect to the each criterion's separate application.

PHP208

OUT WITH THE OLD – IN WITH THE NEW: WOULD NEW SOCIAL PREFERENCE WEIGHTS FOR EQ-5D INEVITABLY REQUIRE A REAPPRAISAL OF PREVIOUS COST-EFFECTIVENESS DETERMINATIONS?

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OBJECTIVES: Social preferences are widely used in economic evaluation required by regulatory agencies. In the UK, NICE requires the use of EQ-5D and its associated set of TTO preference weights for computing QALYs. The weights in question date back nearly two decades. It is reasonable to question whether they continue to represent contemporary social preferences. Were a revised set of EQ-5D weights to be produced then would this necessitate the revision of all past appraisal decisions? This paper presents the 1st phase of work designed to address that question. **METHODS:** The ICER is defined by the ratio of marginal cost (ΔC) /marginal benefit (ΔB). For a given ΔC the ICER falls as ΔB increases. For a given threshold (λ) and for a fixed incremental cost (ΔC), there is a minimum health benefit ΔB_{min} (given by ΔC/λ) which must be achieved to produce an ICER that comes below that threshold limit. TTO-weighted scores were computed for all 243 health states defined by the 3-level version of EQ-5D. A difference matrix was created in which D(i,j) contains the numeric difference between the i^{th} and j^{th} state. The number of differences below a given ΔB_{min} was computed for each column (health state). Threshold values were varied (£20,000-£50,000). Cost differences were varied (£500-£10,000). **RESULTS:** Less than 10% of health state value differences failed to meet the minimum ΔB_{min} of 0.0125 (ΔC =£500; λ=£20,000) indicating susceptability to changes in health state value, however this proportion rose to 57% for higher incremental costs (e.g. ΔC =£3,000). 81/243 health states account for 50% of the differences that exceed ΔB_{min} at all tested levels of ΔC and λ. Graphical representation of these Results can be used to assess the need for reappraisal. **CONCLUSIONS:** For higher cost interventions, relatively small differences in EQ-5D weights can generate ICERs with the propensity to reverse previous cost-effectiveness decisions.

PHP209

DECISION DRIVERS FOR BRAZIL: AN ANALYSIS OF CONITEC RECOMMENDATIONS

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OBJECTIVES: Since its establishment in December 2011, Brazil's HTA body CONITEC (National Commission on the Incorporation of Technologies), has published more than 90 assessments. The objective of the present study was to perform an analysis on CONITEC's positive and negative decisions, in order to understand the main decision drivers. **METHODS:** All assessments published by CONITEC between December 2001 and April 2014 were included in our analysis. The rationale for the decisions was analyzed for both positive and negative recommendations. Reasons for recommending or rejecting a technology were summarized into categories. **RESULTS:** In total, 101 publications were identified: 67 of those assessed drugs, 12 a procedure or intervention and 11 a medical device. The remaining 11 were clinical guidelines (not included in the analysis). Overall, 46 recommendations were positive and 44 negative. The main reasons for rejection were concerns about the economic evidence (23 reports) or lack to demonstrate significant additional clinical benefits (22). The main reasons for positive recommendations were demonstrated clinical efficacy benefit (21), low budget impact (19) and fulfillment of high unmet needs (15). In the majority of cases, the decision was based on multiple factors. **CONCLUSIONS:** Brazil has set the way for a more transparent process for technology assessment following a formal process including pharmacoeconomic guidelines. However, insufficient clinical benefits and methodological concerns about the economic evaluation as major rejection drivers reveals that manufacturers are not yet addressing CONITEC's requirements. Full transparency on the evaluation of outcomes is still missing, providing additional complexity for manufacturers towards a positive recommendation. Our results demonstrated a positive relation between acceptance and demonstrated clinical efficacy, as well as a low budget impact. CONITEC seems to follow a specific pathway in their decision that should be leveraged by manufacturers in order to increase their likelihood of receiving a positive recommendation.

PHP210

THE RISKY BUSINESS OF DRUG DEVELOPMENT: THE FINAL SAY OF NATIONAL HTA AGENCIES ON A PHARMACEUTICAL'S BENEFIT DURING THE LAST STRETCH OF AN EXPENSIVE, LONG-LASTING AND ARDUOUS DEVELOPMENT JOURNEY – AS ILLUSTRATED BY THE DECISIONS OF GERMANY'S GEMEINSAMER BUNDESAUSSCHUSS (G-BA)

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OBJECTIVES: Since 2011 Germany follows a formal process of evaluating new pharmaceuticals for their incremental benefit vs. an appropriate comparator to inform price negotiations with Insurers. This study summarizes the rationale underlying the German authorities' (G-BA) final assessment of manufacturers' submissions following successful approval by regulators. **METHODS:** G-BA decisions (1/2011 to 2/2014) were evaluated for their alignment (full, partial or none) between manufacturer's development programs and expectations concerning: (1) target population; (2) comparator; (3) clinical endpoints, including indirect comparisons. Also addressed was the role of safety and how the G-BA addressed the potential for bias. **RESULTS:** Of 69 completed submissions, 3 were resubmissions and 7 lacked a dossier. 59 completed submissions were subjected to a detailed review. Ten (17%) were for orphan disease indications. Major disagreement existed for 37 (63%), of which 17 (46%) were considered fully inadequate, and 20 (54%) inadequate for significant subgroups. Main reasons for inadequacy were: wrong comparator (27 of 37 [73%], wrong endpoint 6 [16%] and use of historical controls (3 [11%]). For 34 (92%) the major disagreement also led to a lower benefit judgment. All 19 indirect treatment comparisons were considered flawed. Safety was a differentiator for 24 of the 59 submissions, either primary (2) or in addition to efficacy (22). G-BA disagreed with the manufacturer on safety for 12 (50%) of the 24 submissions. **CONCLUSIONS:** This analysis of the first 3 years of G-BA's early benefit appraisal illustrates that a majority of the submissions fail to convince the German authorities despite having obtained licensing approval. A wrong comparator was the main reason for full or partial rejection. Indirect treatment comparisons were never accepted. Decisions taken early in the development program have important repercussions on reimbursement negotiations with authorities in Germany.

PHP211

HTA EPIDEMIOLOGY DATA IN DIFFERENT GEOGRAPHICAL REGIONS: INVESTIGATION OF REQUIREMENTS FOR ONCOLOGY DRUGS

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OBJECTIVES: Harmonisation of health technology assessment (HTA) processes between countries is a logical and efficient solution to complex data gathering exercises required of pharmaceutical manufacturers when preparing submissions. However, harmonisation is a slow process and potentially substantial differences between countries exist. Further, some types of data will inevitably need to be country-specific to meet local HTA requirements. Epidemiological data can be considered one such source of information. **METHODS:** We reviewed HTA requirements in Australia, England and Wales, Japan and Scotland for epidemiology data requirements in their submission. Specific data types were identified and compared across the geographical regions. **RESULTS:** Clear requirements were available for Australia (Pharmaceutical Benefits Advisory Committee [PBAC]), England and Wales (National Institute for Health and Care Excellence [NICE]), and Scotland (Scottish Medicines Consortium [SMC]). As of April 2014, there is an ongoing development